

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported): February 28, 2023

Aurinia Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

Canada
(State or Other Jurisdiction of Incorporation)

001-36421
(Commission File No.)

98-1231763
(IRS Employer Identification No.)

#1203-4464 Markham Street
Victoria, British Columbia
V8Z 7X8
(250) 708-4272
(Address and telephone number of registrant's principal executive offices)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Shares, without par value	AUPH	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On February 28, 2023, Aurinia Pharmaceuticals Inc. (Aurinia) issued a press release announcing its financial results for the quarter and year ended December 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Current Report on Form 8-K and the exhibit hereto are being furnished pursuant to this Item 2.02 and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act), or otherwise subject to the liability of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K and the exhibit hereto, that is furnished pursuant to this Item 2.02 shall not be incorporated by reference in any of Aurinia's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Press release dated February 28, 2023, Announcing Fourth Quarter and Full Year 2022 Financial Results and Company Updates

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 28, 2023

AURINIA PHARMACEUTICALS INC.

By: /s/ Joseph Miller

Name: Joseph Miller

Title: Chief Financial Officer



AURINIA REPORTS FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS AND COMPANY UPDATES

\$28.4 million in total net revenue for the fourth quarter 2022, a 21% increase over fourth quarter 2021 and \$134.0 million for full year 2022, a 194% increase over 2021

Cash, cash equivalents, and investments of \$389.4 million as of December 31, 2022

Conference call to be hosted today at 8:30 a.m. ET

VICTORIA, British Columbia – February 28, 2023 - Aurinia Pharmaceuticals Inc. (NASDAQ: AUPH) (Aurinia or the Company) today issued its financial results for the fourth quarter and the full year ended December 31, 2022. Amounts are expressed in U.S. dollars.

Aurinia achieved total net revenue of \$28.4 million and \$134.0 million for the fourth quarter and full year ended December 31, 2022, respectively. Aurinia achieved net product revenue of \$28.3 million and \$103.5 million for the fourth quarter and full year ended December 31, 2022, respectively.

“2022 was a year of significant growth generating \$134.0 million in total net revenue representing a 194% increase over the previous year. As an organization, we continue to advocate for improved screening, diagnosis and the treatment of lupus nephritis with healthcare providers while reinforcing the clinical benefits of LUPKYNIS over the historic standard of care.” said Peter Greenleaf, President and Chief Executive Officer of Aurinia. “We are focused on operational and commercial execution and are poised for continued growth in and outside the U.S., as we work to change the course of lupus nephritis and other autoimmune diseases.”

For fiscal year 2023, the Company is reiterating its previous net product revenue guidance of \$120 to \$140 million from sales of LUPKYNIS. This range represents a double-digit percentage increase in net product revenue from sales of LUPKYNIS compared to fiscal year 2022.

Fourth Quarter 2022 Highlights & Upcoming Milestones:

- There were approximately 1,525 patients on LUPKYNIS therapy at December 31, 2022, compared with 1,354 at September 30, 2022.
- Aurinia added 406 PSFs during the fourth quarter 2022, a 15% decrease from the fourth quarter 2021 (477), and a 9% increase from third quarter 2022 (374), exiting the year with a total of 1,648 PSFs during 2022.
- Through February 24, 2023, the Company has secured 274 PSFs for a total of approximately 3,500 PSFs since launch.
- Conversion rates continue to improve with approximately 85% of PSFs converted to patients on therapy.
- Time to convert continues to decrease with 30- and 60- day conversion rates at their best levels since launch.
- Launched new direct to patient / consumer campaign focused on patient education and activation.
- Terminated inter partes review of *U.S. Patent No. 10,286,036*.
- Strengthened the LUPKYNIS patent position with the receipt of a Notice of Allowance from the U.S. Patent Trademark Office for an additional method of use patent associated with the LUPKYNIS proprietary dosing regimen (*U.S. Patent Application (No. 17/713,140)*) and notification from the European Patent Office of its intent to grant the European version of the existing U.S. method of use patent (*U.S. Patent No. 10,286,036*) for LUPKYNIS.

Financial Results for the Quarter and Year Ended December 31, 2022

Total net revenue was \$28.4 million and \$23.4 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. Total net revenue was \$134.0 million and \$45.6 million for the years ended December 31, 2022 and December 31,

2021, respectively. The increase in the quarter and full year periods is due to an increase in LUPKYNIS product sales, which was driven predominantly by further penetration in the LN market. The increase for the year ended December 31, 2022 over December 31, 2021 also includes the recognition of a \$30.0 million milestone payment from Otsuka following the European Commission (EC) granting marketing authorization of LUPKYNIS in September 2022.

Total cost of sales and operating expenses for the quarters ended December 31, 2022 and December 31, 2021 were \$56.5 million and \$56.1 million, respectively. Total cost of sales and operating expenses were \$245.5 million and \$226.3 million for the years ended December 31, 2022 and December 31, 2021, respectively. Further breakdown of operating expenses drivers and fluctuations are highlighted in the following paragraphs.

Cost of sales were \$1.4 million and \$0.5 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. Cost of sales were \$5.7 million and \$1.1 million for the years ended December 31, 2022 and December 31, 2021, respectively. The increase for the quarter and full year periods was primarily due to an increase in product related revenue, coupled with an increase in our inventory reserves, which were primarily related to reserves on process validation batches used for FDA approval.

Gross margin for the quarters ended December 31, 2022 and December 31, 2021 was approximately 95% and 98% respectively. Gross margin for the years ended December 31, 2022 and December 31, 2021 was approximately 96% and 98%, respectively.

Selling, general and administrative (SG&A) expenses, inclusive of share-based compensation, were \$47.5 million and \$44.8 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. SG&A expenses, inclusive of share-based compensation, were \$196.4 million and \$173.5 million for the years ended December 31, 2022 and December 31, 2021, respectively. The primary drivers for the increase for the quarter and full year periods ended December 31, 2022 as compared to December 31, 2021 were an increase of professional fees and services mainly related to corporate legal matters and pharmacovigilance; and travel, trade shows and sponsorships to support the commercialization of LUPKYNIS. Additionally, salaries, incentive pay and employee benefits increased due to inflationary increases and routine year over year merit and promotion increases.

Non-cash SG&A share-based compensation expense were \$7.0 million and \$7.2 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. Non-cash SG&A share-based compensation expense were \$28.4 million and \$26.4 million for the years ended December 31, 2022 and December 31, 2021, respectively.

Research and Development (R&D) expenses, inclusive of share-based compensation, were \$9.9 million and \$11.1 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. R&D expenses, inclusive of share-based compensation expense, were \$45.0 million and \$51.1 million for the years ended December 31, 2022 and December 31, 2021, respectively. The primary drivers for the decrease were due to the \$10.0 million upfront license and accrued milestone expense for AUR300 in the prior year, offset partially by additional developmental expenses related to AUR200 and AUR300 for the year ended December 31, 2022. In accordance with U.S. GAAP, AUR200 and AUR300 were recorded as asset acquisitions and expensed as R&D expense at the acquisition dates.

Non-cash R&D share-based compensation income and expense were \$0.3 million and \$1.2 million for quarters ended December 31, 2022 and December 31, 2021, respectively. Non-cash R&D share-based compensation expense were \$3.3 million and \$4.4 million for the years ended December 31, 2022 and December 31, 2021, respectively.

Interest income was \$2.9 million and \$0.1 million for the quarters ended December 31, 2022 and December 31, 2021, respectively. Interest income was \$5.1 million and \$0.5 million for the years ended December 31, 2022 and December 31, 2021, respectively. The increase for the quarter and full year was mainly due to higher yields on our investments as a result of increasing interest rates.

For the quarter ended December 31, 2022, Aurinia recorded a net loss of \$26.0 million or \$0.18 net loss per common share, as compared to a net loss of \$33.3 million or \$0.25 net loss per common share for the quarter ended December 31, 2021. For the

year ended December 31, 2022, Aurinia recorded a net loss of \$108.2 million or \$0.76 net loss per common share as compared to a net loss of \$181.0 million or \$1.40 net loss per common share for the previous period.

Financial Liquidity at December 31, 2022

As of December 31, 2022, Aurinia had cash, cash equivalents and restricted cash and investments of \$389.4 million, compared to \$466.1 million at December 31, 2021. The decrease in cash, cash equivalents and restricted cash and investments is primarily related to the continued investment in commercialization activities, advancement of our pipeline and a payment for the achievement of a one-time milestone, partially offset by an increase in cash receipts from the sale of LUPKYNIS and the achievement of a \$30.0 million one-time milestone upon the EC granting marketing authorization of LUPKYNIS in September 2022.

Aurinia believes that it has sufficient financial resources to fund its operations, which include funding commercial activities, including FDA related post approval commitments, manufacturing and packaging commercial drug supply, funding its commercial infrastructure, advancing its R&D programs and funding its working capital obligations for at least the next few years.

This press release is intended to be read in conjunction with the Company's consolidated financial statements and Management's Discussion and Analysis for the year ended December 31, 2022 in the Company's Annual Report on Form 10-K, which will be accessible on Aurinia's website at www.auriniapharma.com, on SEDAR at www.sedar.com or on EDGAR at www.sec.gov/edgar.

Conference Call Details

Aurinia will host a conference call and webcast to discuss the quarter and year ended December 31, 2022 financial results today, Tuesday, February 28, 2023 at 8:30 a.m. ET. The audio webcast can be accessed under "News/Events" through the "Investors" section of the Aurinia corporate website at www.auriniapharma.com. In order to participate in the conference call, please dial +1-877-407-9170 (Toll-free U.S. & Canada).

About Lupus Nephritis

Lupus nephritis is a serious manifestation of systemic lupus erythematosus (SLE), a chronic and complex autoimmune disease. About 200,000-300,000 people live with SLE in the U.S. and about one-third of these people are diagnosed with lupus nephritis at the time of their SLE diagnosis. About 50 percent of all people with SLE may develop lupus nephritis. If poorly controlled, lupus nephritis can lead to permanent and irreversible tissue damage within the kidney. Black and Asian people with SLE are four times more likely to develop lupus nephritis and Hispanic people are approximately twice as likely to develop the disease compared to White people with SLE. Black and Hispanic people with SLE also tend to develop lupus nephritis earlier and have poorer outcomes, compared to White people with SLE.

About Aurinia

Aurinia Pharmaceuticals is a fully integrated biopharmaceutical company focused on delivering therapies to treat targeted patient populations that are impacted by autoimmune, kidney and rare diseases with a high unmet medical need. In January 2021, the Company introduced LUPKYNIS® (voclosporin), the first FDA-approved oral therapy dedicated to the treatment of adult patients with active lupus nephritis. The Company's head office is in Victoria, British Columbia, its U.S. commercial office is in Rockville, Maryland. The Company focuses its development efforts globally.

Forward-Looking Statements

Certain statements made in this press release may constitute forward-looking information within the meaning of applicable Canadian securities law and forward-looking statements within the meaning of applicable United States securities law. These forward-looking statements or information include but are not limited to statements or information with respect to: Aurinia's estimates as to annual net product revenue from sales of LUPKYNIS in the range of \$120-\$140 million in 2023; Aurinia's

estimates as to the number of patients with SLE in the U.S. and the proportion of those persons who will develop LN; Aurinia being confident that it is poised for growth and product expansion; and Aurinia's belief that it has sufficient financial resources to fund its current plans for at least the next few years. It is possible that such results or conclusions may change. Words such as "anticipate", "will", "believe", "estimate", "expect", "intend", "target", "plan", "goals", "objectives", "may" and other similar words and expressions, identify forward-looking statements. We have made numerous assumptions about the forward-looking statements and information contained herein, including among other things, assumptions about: the accuracy of reported data from third party studies and reports; the number, and timing of receipt, of PSFs and their rate of conversion into patients on therapy; that Aurinia's intellectual property rights are valid and do not infringe the intellectual property rights of third parties; Aurinia's assumptions relating to the capital required to fund operations; the assumption that Aurinia's current good relationships with its suppliers, service providers and other third parties will be maintained; assumptions relating to the burn rate of Aurinia's cash for operations; assumptions related to timing of interactions with regulatory bodies; and that Aurinia's third party service providers will comply with their contractual obligations. Even though the management of Aurinia believes that the assumptions made, and the expectations represented by such statements or information are reasonable, there can be no assurance that the forward-looking information will prove to be accurate.

Forward-looking information by their nature are based on assumptions and involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance, or achievements of Aurinia to be materially different from any future results, performance or achievements expressed or implied by such forward-looking information. Should one or more of these risks and uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in forward-looking statements or information. Such risks, uncertainties and other factors include, among others, the following: Aurinia's actual future financial and operational results may differ from its expectations; difficulties Aurinia may experience in completing the commercialization of voclosporin; the market for the LN business may not be as estimated; Aurinia may have to pay unanticipated expenses; Aurinia may not be able to obtain sufficient supply to meet commercial demand for voclosporin in a timely fashion; unknown impact and difficulties imposed by the COVID-19 pandemic on Aurinia's business operations including nonclinical, clinical, regulatory and commercial activities; the results from Aurinia's clinical studies and from third party studies and reports may not be accurate; Aurinia's third party service providers may not, or may not be able to, comply with their obligations under their agreements with Aurinia; regulatory bodies may not grant approvals on conditions acceptable to Aurinia and its business partners, or at all; and Aurinia's assets or business activities may be subject to disputes that may result in litigation or other legal claims. Although Aurinia has attempted to identify factors that would cause actual actions, events, or results to differ materially from those described in forward-looking statements and information, there may be other factors that cause actual results, performances, achievements, or events to not be as anticipated, estimated or intended. Also, many of the factors are beyond Aurinia's control. There can be no assurance that forward-looking statements or information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, you should not place undue reliance on forward-looking statements or information.

All forward-looking information contained in this press release is qualified by this cautionary statement. Additional information related to Aurinia, including a detailed list of the risks and uncertainties affecting Aurinia and its business, can be found in Aurinia's most recent Annual Report on Form 10-K available by accessing the Canadian Securities Administrators' System for Electronic Document Analysis and Retrieval (SEDAR) website at www.sedar.com or the U.S. Securities and Exchange Commission's Electronic Document Gathering and Retrieval System (EDGAR) website at www.sec.gov/edgar, and on Aurinia's website at www.auriniapharma.com.

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AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(in thousands)

	<u>December 31, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	\$ 94,172	\$ 231,900
Short-term investments	295,218	234,178
Accounts receivable, net	13,483	15,414
Inventories, net	24,752	19,326
Prepaid expenses	13,580	11,710
Other current assets	1,334	796
Total current assets	442,539	513,324
Non-current assets:		
Other non-current assets	13,339	11,838
Property and equipment, net	3,650	4,418
Acquired intellectual property and other intangible assets, net	6,425	8,404
Right-of-use assets, net	4,907	5,383
Total assets	\$ 470,860	\$ 543,367
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued liabilities	39,990	34,947
Deferred revenue	3,148	190
Other current liabilities	2,033	4,450
Operating lease liabilities	936	1,059
Total current liabilities	46,107	40,646
Non-current liabilities:		
Deferred compensation and other non-current liabilities	12,166	15,950
Operating lease liabilities	7,152	7,680
Total liabilities	65,425	64,276
Shareholders' Equity:		
Common shares - no par value, unlimited shares authorized, 142,268 and 141,600 shares issued and outstanding at December 31, 2022 and 2021, respectively	1,185,309	1,177,051
Additional paid-in capital	85,489	59,014
Accumulated other comprehensive loss	(1,061)	(852)
Accumulated deficit	(864,302)	(756,122)
Total shareholders' equity	405,435	479,091
Total liabilities and shareholders' equity	\$ 470,860	\$ 543,367

AURINIA PHARMACEUTICALS INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Three months ended		Years ended	
	December 31, 2022	December 31, 2021	December 31, 2022	December 31, 2021
	(unaudited)			
Revenue:				
Product revenue, net	\$ 28,326	\$ 23,375	\$ 103,468	\$ 45,488
License and collaboration revenue	109	29	30,562	117
Total revenue, net	<u>28,435</u>	<u>23,404</u>	<u>134,030</u>	<u>45,605</u>
Operating expenses:				
Cost of sales	1,362	481	5,664	1,091
Selling, general and administrative	47,473	44,764	196,371	173,536
Research and development	9,870	11,149	44,988	51,139
Other (income) expense, net	(2,170)	(285)	(1,523)	574
Total cost of sales and operating expenses	<u>56,535</u>	<u>56,109</u>	<u>245,500</u>	<u>226,340</u>
Loss from operations	<u>(28,100)</u>	<u>(32,705)</u>	<u>(111,470)</u>	<u>(180,735)</u>
Interest income	2,909	109	5,118	529
Net loss before income taxes	<u>(25,191)</u>	<u>(32,596)</u>	<u>(106,352)</u>	<u>(180,206)</u>
Income tax expense	855	726	1,828	760
Net loss	<u>\$ (26,046)</u>	<u>\$ (33,322)</u>	<u>\$ (108,180)</u>	<u>\$ (180,966)</u>
Basic and diluted loss per common share	<u>\$ (0.18)</u>	<u>\$ (0.25)</u>	<u>\$ (0.76)</u>	<u>\$ (1.40)</u>
Weighted-average common shares outstanding used in computation of basic and diluted loss per share	<u>141,909</u>	<u>132,054</u>	<u>141,915</u>	<u>129,369</u>